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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	09/913,752	FERCEJ TEMELJOTOV ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71,72 and 76-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71,72 and 76-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The Examiner acknowledges receipt of the amendments filed on 12/01/2008 wherein claims 80, 82 and 84 have been amended and claim 70 has been cancelled.

2. Claims 71, 72 and 76-84 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

3. Applicants arguments filed 12/01/2008 regarding the rejection of claim 70 made by the Examiner under 35 USC 112, first paragraph have been fully considered and they are found persuasive. The rejection has been overcome by cancellation of the claim.

4. Applicants arguments filed 12/01/2008 regarding the rejection of claim 70 made by the Examiner under 35 USC 103(a) over Akiyama et al. (WO 98/42311) in view of Farah et al. (WO 98/14176) evidenced by the US equivalent to US 61940056 have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claim.

5. Applicants arguments filed 12/01/2008 regarding the rejection of claims 72, 76-78 and 80-83 made by the Examiner under 35 USC 103(a) over Briskin (WO 95/22319) in view of Gibson et al. (US 5811120), evidenced by Methocel and WO 98/42311 have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

6. Applicants arguments filed 12/01/2008 regarding the rejection of claims 70 and 71 made by the Examiner under 35 USC 103(a) Briskin (WO 95/22319) in view of Gibson et al. (US 5811120), evidenced by Methocel and WO 98/42311, in further view of Evenstad et al. (US

5126145) have been fully considered and they are found persuasive. This rejection has been overcome by amendment. Note claim 70 has been overcome by cancellation of the claim.

7. Applicants arguments filed 12/01/2008 regarding the rejection of claim 79 made by the Examiner under 35 USC 103(a) over Briskin (WO 95/22319) in view of Gibson et al. (US 5811120), evidenced by Methocel and WO 98/42311, in further view of Khan et al. (US 5656296) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

8. Applicants arguments filed 12/01/2008 regarding the rejection of claim 71,72 and 76-84 made by the Examiner under 35 USC 112, first paragraph have been fully considered and they are found persuasive.

9. Note, claim 71 is being interpreted as dependent from claim 82.

10. The rejection of claims 71,72 and 76-84 made by the examiner under 35 USC 112, first paragraph is **MAINTAINED** for the reasons of record in the office action mailed on 07/30/2008.

11. In regards to the 112, first paragraph rejection, Applicant asserts the following:

A) Applicant have support for "about 42%" and "about 43%" and that there is no *in haec verba* requirement for said limitation but support may be through express, implicit, or inherent disclosure.

12. In response to A, the Examiner respectfully disagrees Applicant is correct in that there is no *in haec verba* requirement for said limitation and that support may be through express, implicit, or inherent disclosure, however, there is a lack of explicit, implicit or inherent written support for the broader scope of the presently claimed limitations of "about 42% and "about

47%" . The term 'about' encompasses value slightly higher and slightly lower that the value recited. For instance, 'about 42%' may encompass a value of 41%, 40%, 39%, 38%, etc. However, such values are not taught by the instant specification. In fact, no values are described by Applicant in their specification that provide sufficient support for the limitations 'about 42%' or 'about 43%'. It cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See In re Smith 173 USPQ 679, 683 (CCPA 1972). It's noted that Applicant does not provide any general range in the specification for the amount of clarithromycin. Thus, as there is no explicit, implicit or inherent disclosure of the broader scope of "about 42% and "about 47" sufficient to provide adequate written support for the present limitations, the claims as written lack sufficient written description. Applicant is reminded that they only have support for 43.47% and 42.01% by weight of clarithromycin in their composition. Thus, applicants' argument's are not found persuasive.

13. Applicants arguments filed 12/01/2008 regarding the rejection of claims 71, 72 and 76-84 made by the Examiner under 35 USC 103(a) over Akiyama et al. (WO 98/42311) in view of Farah et al. (WO 98/14176) evidenced by the US equivalent to US 61940056 have been fully considered but they are not found persuasive.

14. Note, claim 71 will be interpreted as depending from claim 82.

15. The rejection of claims 71,72 and 76-84 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 12/01/2008.

16. In regards to the 103(a) rejection, Applicant asserts the following:

B) Applicant argues that a person of ordinary skill would not be capable of arriving at a the presently claimed invention due to innumerable possibilities taught by Akiyama; and

C) Akiyama does not teach or require that their composition comprise low-viscosity HPMC.

17. In response to B, Akiyama teaches that their composition comprise an active material, glyceryl fatty component and a viscogenic agent. The active material is taught to be several things, one of which is clarithromycin. And the viscogenic agent may be selected from a variety of naturally and non-naturally occurring polymers. Hydroxypropylmethylcellulose (HPMC) is an exemplified viscosity enhancing agent. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. See MPEP 2123(II). Moreover, the use of patents as reference is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, and are relevant for all that they contain. See MPEP 2123(I). Thus, the fact that Akiyama encompasses many possible compositions, the composition in general comprises an active material, glyceryl fatty component and a viscogenic agent. And any person of ordinary skill in the art would capable of looking at the lists provided by the teaching and select the instantly claimed species with a reasonable expectation for success.

18. In response to C, this argument is not persuasive. The present specification defines a 'low-viscosity' agent as an agent when dissolved in water at 2% results in a viscosity of between 40 cP and 20000 cP. The teaching of Akiyama is identical. Akiyama, while not specifically using the phrase 'low-viscosity' before HPMC, the viscous agent is itself to be low viscosity. HPMC is contemplated as a potential viscous agent. Moreover, Akiyama low-viscosity agent is an agent that when dissolved in water at 2% results in about 3 cP to about 50000 cP. Thus, the substantial overlap of viscosities would suggest to any person of ordinary skill that the polymer

employed by Akiyama are in fact low-viscosity. Therefore, there would be no reason to expect that HPMC contemplated by Akiyama does not in fact have a low viscosity.

Maintained Rejections, of Record
Claim Rejections - 35 USC § 112

19. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20. **Claims 71-72 and 76-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 71 has been interpreted as depending from claim 82.**

21. Claim 80 and claim 82 recite "about 42%" of clarithromycin which does not have support in the specification as originally filed. Applicant does not have support for the term "about". The phrase "about 42%" encompasses any concentration slightly over and slightly under 42%, which Applicant does not have support for.. Example 1 incorporates clarithromycin in an amount of 43.47%; examples 2 and 3 in an amount of 42.01%; example 4 in an amount of 43.47%; and example 5 in an amount of 43.47%. It is noted that applicant does not provide any general range in the specification. However, applicant does have support for 42.01% and 43.47% clarithromycin.

22. Claim 80 recites "wherein the components are combined to allow the glycerol behenate to form the matrix and wherein the hydroxypropyl methylcellulose and the clarithromycin component are dispersed within the matrix", does not have support in the specification as originally filed. It is noted that page 4, line 22 to page 5, line 5 discloses that the water-insoluble component [glyceryl behenate], the hydrophilic component, and the drug form the matrix.

23. Claim 84 is directed to weight percents that are not disclosed in the originally field specification or claims. The recitation "about 22%" glyceryl behenate and "about 17%" hydroxypropylmethylcellulose does not have support. The phrase "about 43%" of clarithromycin encompasses any concentration slightly over or slightly under 43%. Example 1 incorporates clarithromycin in an amount of 43.47%; examples 2 and 3 in an amount of 42.01%; example 4 in an amount of 43.47%; and example 5 in an amount of 43.47%. Applicant does not have support for these terms or the values encompassed therein. It is noted that applicant does not provide any general range in the specification. However, applicant does have support for 42.01% and 43.47% clarithromycin.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. **Claims 71-72 and 76-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (WO 98/42311) in view Farah et al. (WO 98/14176; US 6194005 is used as translation). Claim 71 has been interpreted as depending from claim 82.**

26. Akiyama et al teach a gastrointestinal mucosa adherent matrix adapted to stay long in the gastrointestinal tract for sustained drug release. The gastrointestinal mucosa-adherent matrix which is solid at ambient temperature includes a matrix in which each matrix particle containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient has a coating layer comprising or containing the viscogenic agent.

27. Examples of viscogenic agent include polymers containing carboxyl groups or salts thereof, cellulose ethers, polyethylene glycols having molecular weights not less than 200,000, and naturally-occurring mucous substances. The preferable viscogenic agents are those having a viscosity in the range of 3 to 50,000 cps, preferably 10 to 30,000 cps, and more preferably 15 to 30,000 cps as a 2 percent by weight aqueous solution thereof at 20.degree. C. Cellulose ethers taught include hydroxymethylcellulose and hydroxypropylmethylcellulose. See page 17, lines 10-35 and page 18, line 36. The viscogneic agent is taught in a preferable amount of 1-20%. See page 19, lines 10-15. HPMC is taught on page 18.

28. The matrix may be made of polyglycerol fatty acid ester be about 15 to 80.degree. C., preferably about 30 to 75.degree. C. and more preferably about 45 to 75.degree. C or lipids having a melting point of 40 to 120.degree. C., preferably 40 to 90.degree. C. The polyglycerol fatty acid esters include behenyl glycerides and the lipids include glycerol fatty acid esters wherein behenic acid is taught as a fatty acid. See page 8, lines 1-5, page 10, and page 12, lines 8-36 .The lipid is utilized in an amount of 5-98%.

29. The active includes antimicrobial substance and preferably clarithromycin. See page 14, lines 25-30 and page 15, lines 1-2. The active is used in an amount of 0.005-95% and preferably about 10 to about 50%. See page 26, lines 12-20.

30. The solid composition may be coated with a coating material including hydroxypropylmethylcellulose phthalate. See page 22, lines 15-25 and page 23, lines 30-35. The solid dosage form includes tablets. See page 25, line 14. The composition includes surfactants. See page 29, lines 1-15. The examples provide the method of making the composition.

31. Akiyama does not specify the glycerol fatty acid ester.

32. Farah teaches a method for preparing a pharmaceutical composition with modified release of the active principle, comprising a matrix as lipid matrix agent, of an ester of behenic acid and of alcohol. The alcohol is advantageously chosen from the group comprising glycerol, polyglycerol, propylene glycol, propylene glycol in combination with ethylene oxide and polyethylene glycol. These matrix agents exhibit the advantage of having a melting point of greater than 50.degree. C., which prevents them from disintegrating at the compression temperature. Furthermore, this melting point is greater than the internal temperature of the human body (37.degree. C.), which allows the lipid agent to have a more pronounced matrix behavior. The lipid is used in an amount of 1-15%. See column 4, lines 10-55. Glycerol behenate is the preferred lipid for the matrix.

33. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Akiyama and Farah and utilize glycerol behenate in Akiyama's composition. One would have been motivated to do so with a reasonable expectation of success and similar results since Akiyama teaches the use of lipids with a melting

point of 40-120 degrees C such as glycerol fatty acid esters for the matrix and Farah teaches glycerol behenate may be used to form a lipid matrix in sustained release composition. Further, Farah teaches the esters of behenic acid and alcohol may used wherein the alcohol may be glycerol or polyglycerol. Thus, Farah teaches that both the polyglycerols of fatty acid esters and glycerol of fatty acid esters may be used to form the matrix and therefore establishes the functional equivalency. Therefore, it would have been obvious to substitute one lipid matrix forming material with another similar lipid matrix forming material.

34. Regarding claim 84, Akiyama teaches the active in an amount of about 0.005-95%, preferably about 1-95%, more preferably about 10-95%, and most preferably about 10-50%. This range overlaps the instant range of at least about 43%. Akiyama incorporates viscogenic agent is incorporated preferably amount of the viscogenic agent is 1-20%, which encompasses "about 17%". Thus, it is within the skill of an artisan to manipulate the concentration based on the general range provided by the prior art absent evidence of the unexpectedness of the claimed range. One would have been motivated to do so during routine optimization Further, Akiyama incorporates the lipid in an amount of 5-98% and Farah teaches 1-15%. Thus, it is within the skill of an artisan to manipulate the concentration based on the general range provided by the prior art and absent evidence of unexpectedness of the instant amount. One would have been motivated to do so depending on the desired release profile.

New Rejections, Necessitated by Amendment

Claim Objections

35. Claim 71 is objected to because of the following informalities: depends from a cancelled claim. Appropriate correction is required.Claim 71 is objected to because of the following

informalities: unclear language. Claim 71 recites, "of about up to about". Applicant is requested to remove the first 'about' in the sentence for clarity.

Claim Rejections - 35 USC § 103

36. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

37. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

38. **Claims 71, 72, 76-78 and 80-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briskin et al. (WO 95/22319; of record) in view of Gibson et al. (US 5811120; of record) and Evenstad et al. (US 5126145; of record), evidenced by METHOCEL and WO 98/42311. Claim 71 has been interpreted as depending from claim 82.**

39. Briskin teaches preparing pharmaceutical composition comprising up to 90% of an active agent, 1-75% of an extrusion aid including glyceryl behenate, hydrogenated vegetable oil, fats, fatty acid esters, fatty acids, etc. The composition further contains binding agents including polyvinylpyrrolidone (povidone K90), carboxymethylcellulose, and hydroxymethylcellulose (HMC) to retard release. See page 4-5. Briskin teaches an oral composition containing 43.4% clarithromycin, 5.5% povidone, 26% carbopol, 5% hydroxypropyl cellulose (an alkyl-substituted cellulose ether), 10% glyceryl behenate, and 10% microcrystalline cellulose. See table 1 on page 8. Specifically example 1b. Note that example 1b contains 5.5% povidone and 5% hydroxypropylcellulose, which comprises a total of 10.5% of the binder.

40. The composition is then formulated in to a tablet or capsule. See page 7, line 7. On page 6, the method of making the tablet is disclosed wherein the *all* the ingredients are blended thoroughly, granulated, and then the particles are formed into tablets. Briskin discloses on page 5, lines 34-35 an enteric coating. Note that enteric coating is inherently acid resistant coating.

41. Briskin teaches the use of hydrophilic binders, specifically HMC and PVP (povidone) as the hydrophilic binder, however Briskin does not the use of low-viscosioty hydroxypropylmethylcellulose (HPMC). Further, Briskin does not teach instant surfactant.

42. Gibson et al teach pharmaceutical formulations containing raloxifene. Gibson et al teaches the conventional additives in pharmaceutical formulations such as hydrophilic binders. Gibson teaches the term "hydrophilic binder" represents binders commonly used in the formulation of pharmaceuticals, such as polyvinylpyrrolidone (PVP), polyethylene glycol, sucrose, dextrose, corn syrup, polysaccharides (including acacia, tragacanth, guar, and alginates), gelatin, and cellulose derivatives (including hydroxypropyl methylcellulose, hydroxypropyl

cellulose, and sodium carboxymethylcellulose). See column 3, lines 50-60. Further, Gibson teaches the use of surfactants including sodium docosate. See column 3, lines 60-67. Further, the reference teaches that the preparation of the oral formulations is well known in the art such as direct compression. The process includes mixing the active with the hydrophilic binder and surfactant, which is then, milled if necessary, drying the granules, and compressing into tablets (col. 5, lines 10-15).

43. Evenstad teaches a controlled release tablet. Evenstad teaches the use of high viscosity HPMC to provide sustain release whereas a water-soluble pharmaceutical binder such as HPMC having binding properties has a much lower viscosity; typically a viscosity of less than 100 cps such as METHOCEL E15. See column 3, lines 5-67. METHOCEL E15 has a viscosity of 12-18 cps.

44. Therefore, it would have been obvious of one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin, Gibson and Evenstad with a reasonable expectation for success in arriving at a tablet composition comprising glyceryl behenate, low viscosity HPMC and calirthromycin. One would have been motivated to substitute Briskin's hydrophilic binders (cellulose derivative HMC and Povidone) for instant cellulose derivative (HPMC) with a reasonable expectation of similar results since Gibson teaches that HPMC, HMC and Povidone are conventional hydrophilic binders utilized in pharmaceutical compositions. Therefore, it is prima facie obvious for a skilled artisan to substitute one functional equivalent with another known functional equivalent with the expectation of similar results and success since the art establishes that both are hydrophilic and act as binders in the composition. The examiner points out that Briskin teaches the binder in a total weight percent of 10.5 (5.5%

povidone and 5% hydroxypropylmethylcellulose). Thus, it is the examiner's position that the prior art's 10.5% reads on the claimed "about 13%". It is noted that the term "about" is not defined in the specification to mean exactly. See MPEP 2111.01. Moreover, it is within the skill of an artisan to manipulate the amount of the binder, which is taught to retard the release in the composition. One would have been motivated to do so depending on the desired release rate.

45. Additionally, Gibson teaches the conventional use of surfactants such as instant sodium docusate in pharmaceutical compositions. Thus, the use of conventional additives in the preparation of pharmaceuticals is prima facie obvious.

46. Regarding claim 82, the combination of the Briskin and Gibson would provide a composition that forms a viscous layer since this is a natural property of HPMC. METHOCEL data sheet discloses METHOCEL of varying viscosities has the ability to form a gel layer. Further, it should be noted that HPC taught by Briskin also is capable of forming a viscous layer as evidenced by WO 98/42311.

47. With respect to the use of low-viscosity HPMC, one would have been motivated to do so since Evenstad teaches high viscosity HPMC is useful for its sustaining action and low viscosity HPMC is useful for its binding properties. Therefore, a skilled artisan would have been motivated to utilize a low viscosity HPMC with a reasonable expectation of similar results since both Briskin and Gibson teach the use of the cellulose derivative for its binding property and Evenstad teaches the low viscosity cellulose derivative provide this function.

48. **Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over Briskin et al. (WO 95/22319) in view Gibson et al. (US 5811120) and Evenstad et al. (US 5126145), as evidenced by METHOCEL and WO 98/42311, in further view of Khan et al. (US 5656296).**

49. Briskin teaches the composition may be coated with an enteric coating or other coatings. See page 5, lines 30-35.

50. The combined references do not teach a coating comprising the instant polymers, i.e. HPMC-phyhalate.

51. Khan teaches a dual control sustained release drug delivery system. Khan teaches the delivery system is coated with a coating layer comprising a water insoluble polymer and water-soluble film forming polymers including cellulose derivatives such as hydroxypropylcellulose, hydroxypropyl-methylcellulose, hydroxypropylmethylcellulose phthalate, sodium carboxymethylcellulose, and the like, and mixtures thereof. See column 6, lines 30-60.

52. It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Briskin, Gibson, Evenstad and Khan with a reasonable expecatiton for success in arrigin with a coating layer comprising a mixture of polymers such as HPMC-phyhalate. One would have been motivated to do so to provide a sustained release effect to the composition. Further, a skilled artisan would have reasonably expected success since Briskin teaches the use of various coating layers.

Conclusion

53. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

54. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

55. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

56. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

57. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
May 12, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643